

Notice of Allowability

Application No.

10/797,349

Examiner

Binta M. Robinson

Applicant(s)

BROSTROM, LYLE

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the IDS filed 6/17/04.
2. ☒ The allowed claim(s) is/are 1-2, 4-9 (now renumbered as claims 1-7).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

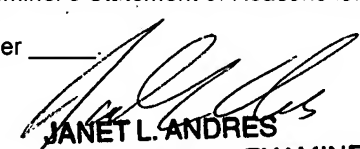
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 6/17/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 7/27/06
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER

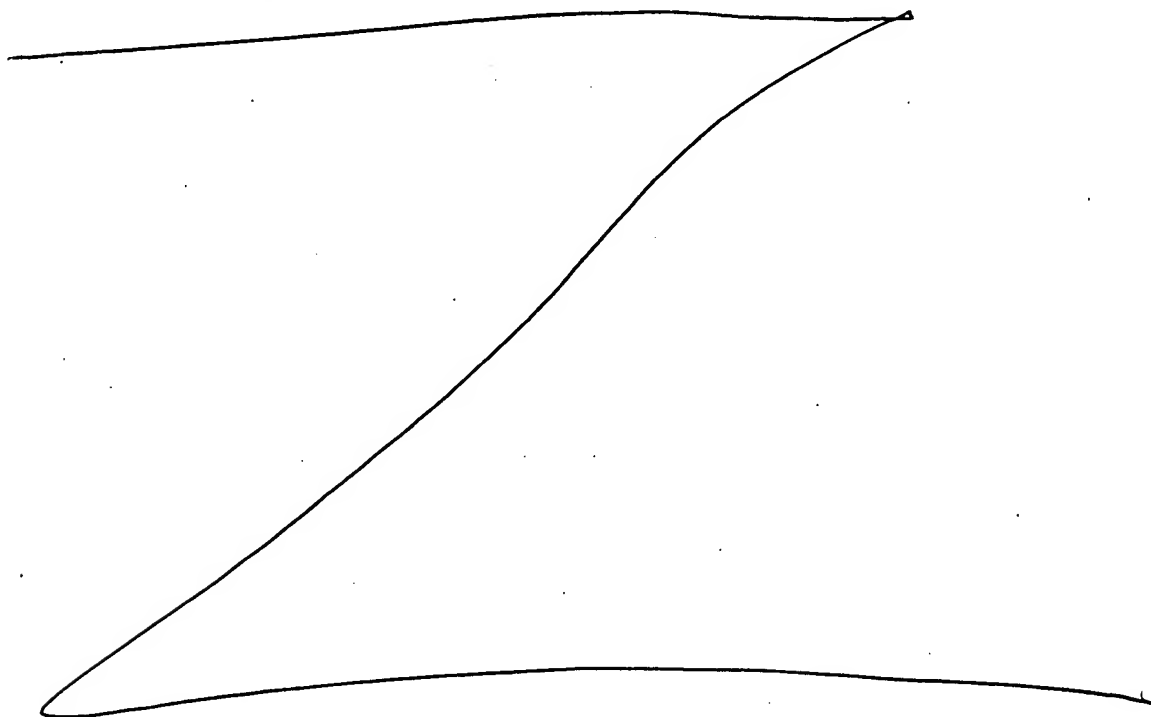
EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Polster, II on July 27, 2006 and May 31, 2007.

The application has been amended as follows:

- A. In claim 1, line 3, page 34, the following diagram is inserted after the term "Fig. 6;"



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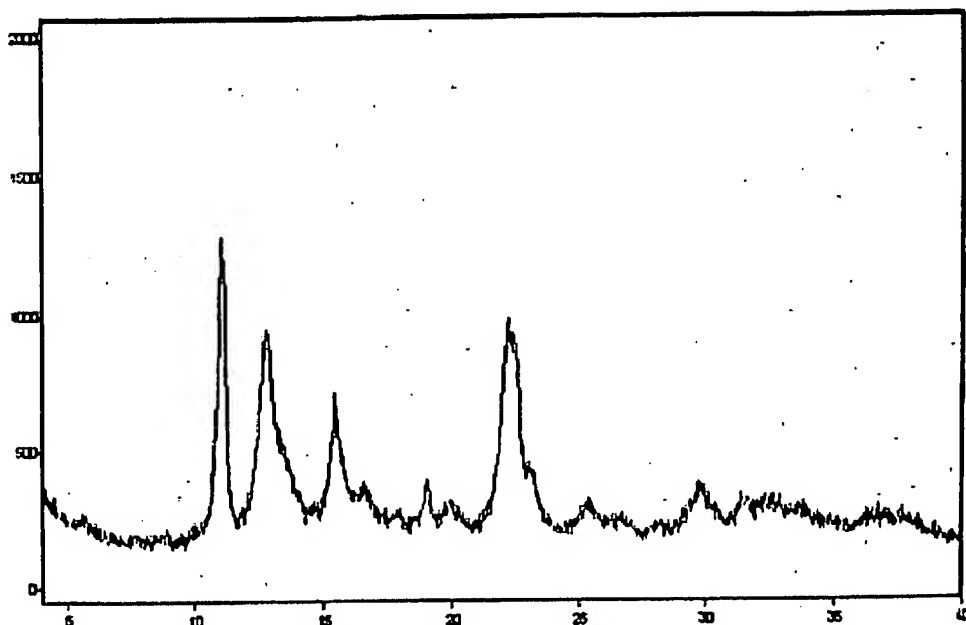
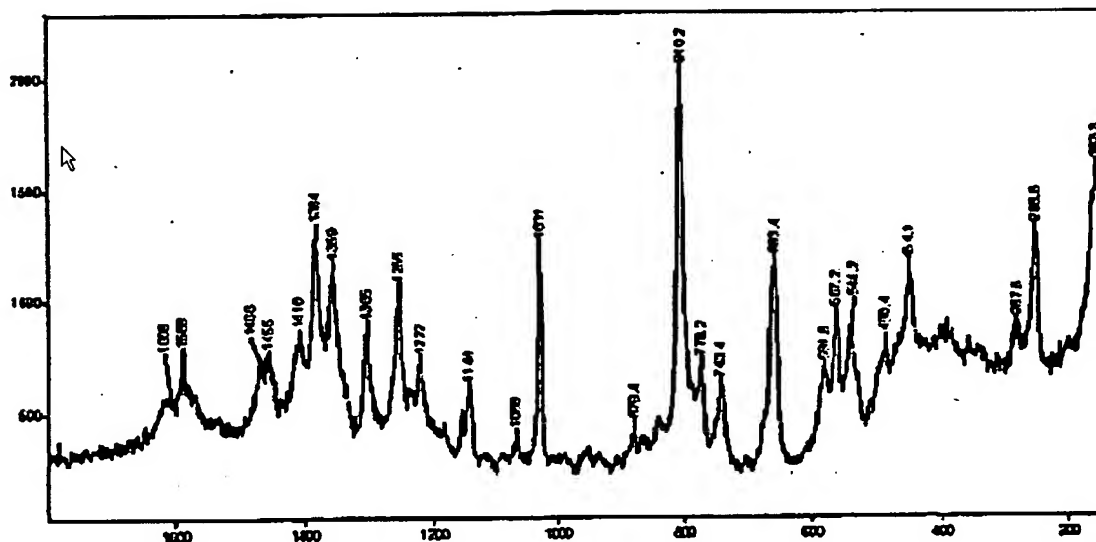


Fig. 6 X-ray powder pattern of Example 10

B. In claim 1, line 3, page 34, the following diagram is inserted after the term "Fig. 12",

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**Fig. 12**

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C. In claim 1, line 4, page 34, the following Table is inserted after the phrase "Table 5"

Table 5: Elemental Analysis of Salicylate monohydrate Salt Examples 9 and 10

Element	Example 12 (THF)	Example 13 (ACN)	Theory 1:1 monohydrate
Carbon	50.53	48.13 / 48.12	47.99
Hydrogen	7.23	6.83 / 6.88	6.71
Nitrogen	10.77	11.53 / 11.46	11.19
Sulfur	7.96	8.61 / 8.61	8.54
Water (KF)	-	4.75	4.79

D. Claim 3 is cancelled without prejudice to the applicant filing a divisional application on that claim.

E. Claim 2 is cancelled without prejudice to the applicant filing a divisional application on that claim.

F. In claim 5, line 2, page 34, the phrase "monohydrate comprising" is amended to -----monohydrate of claim 1 comprising-----.

Examiner's Comment

Applicant is now required to submit a substitute declaration or oath to correct the deficiencies set forth: The Declaration states, "[w]e believe we are the original, first and joint inventors..." However, only one inventor is named.

The substitute oath or declaration must be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" (PTO-37). Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136. Failure to timely file the substitute declaration (or oath) will result in **ABANDONMENT** of the application. The transmittal letter accompanying the declaration (or oath) should indicate the date of the "Notice of Allowance" (PTOL-85) and the application number in the upper right hand corner.

Reasons For Allowance

The following is an examiner's statement of reasons for allowance: The closest prior art reference is Webber et. al. (See Reference N). The difference between the Webber salt and the instantly claimed salt is the substitution on the benzoic acid moiety of the salt. In the instant salt, the benzoic acid moiety is substituted at the 2 – position of the phenyl ring with a hydroxyl group. In the Webber salt, the benzoic acid moiety is unsubstituted at the 2 - position. At columns page 104, lines 15-22, example 65 and at page 106, line 4, see the salt, L-Cysteine, S-[2-[(1-iminoethyl)amino]ethyl]-2-methyl-,benzoate.

The prior art reference does not teach nor suggest to one of ordinary skill in the art how to modify the prior art salt to derive the instant salt.

Therefore, the claims are allowable therefrom.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Thomas Mckenzie can be reached on 571-272-0670.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.

A handwritten signature in cursive script, appearing to read "Binta Robinson".

BMR
June 7, 2007